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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,129	10/10/2003	Stacey L. Schultz-Cherry	800.039US1	1211

21186 7590 11/10/2005

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/684,129	**Applicant(s)** SCHULTZ-CHERRY ET AL.
	Examiner Shanon Foley	**Art Unit** 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date *7/30/04, 8/20/04*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8-20 and 22-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Schultz-Cherry et al. (US 6,696,562 B1)

The applied reference has two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are drawn to a method of identifying an animal exposed to turkey astrovirus-2 and a method of detecting TAstV-2 antibodies (TAstV-2) by providing a fluid sample from a suspected host animal, contacting the sample with an antigen from TAstV-2 and detecting whether the sample comprises antibodies specific for the antigen from TAstV-2. The antigen is the TAstV-2 capsid protein. The fluid sample is blood, serum, urine, feces, saliva or homogenized tissue from the thymus, bursas, intestines taken from a chicken, breeder or a mammal. The antigen is present in recombinant insect cells that are fixed or the antigen is attached to a substrate. Sample antibodies are detected by conventional immunoassays with secondary antibodies labeled with a reporter substrate.

Schultz-Cherry et al. anticipate a method of identifying an animal exposed to turkey astrovirus-2 and a method of detecting TAstV-2 antibodies (TAstV-2) by providing a fluid sample from a suspected host animal, contacting the sample with an antigen from TAstV-2 and detecting whether the sample comprises antibodies specific for the antigen from TAstV-2, see column 10, lines 16-61 and column 11, lines 14-42. Although Schultz-Cherry et al. teach amplification and detection of the TAstV-2 capsid protein by RT-PCR in the working examples, the antibody-antigen detection assays reviewed by Schultz-Cherry et al. in columns 10-11 are taught to detect any TAstV-2 disclosed antigen. The fluid sample is blood, serum, urine, feces, saliva (see column 10, lines 29-32) or homogenized tissue from the thymus, bursas, intestines (see column 5, lines 13-44, column 6, lines 54-55, column 10, lines 21-23 and column 12, lines 13-42) taken from avians (see column 5, lines 53-60). The antigen is present in recombinant insect cells that are fixed or the antigen is attached to a substrate. Sample antibodies are detected by conventional immunoassays with secondary antibodies labeled with a reporter substrate. See the previous citations in columns 10-11 as well as column 9, lines 51-52.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 7 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz-Cherry et al. *supra*.

Claims 6 and 7 state that the test sample is taken from a breeder or a mammal.

Although Schultz-Cherry et al. do not specifically mention detecting TAstV-2 in a breeder or a mammal, the fluid or tissue samples used in the antibody-antigen detection methods discussed in columns 10-11 or in the RT-PCR detection method of claim 6 is not limited to avians. Further, the ordinary artisan would have been motivated to detect the presence of TAstV-2 with a reasonable expectation of success in other animals since astroviruses are known to infect mammals, see Table 1 in column 16 of Schultz-Cherry et al. for example.

Claims 27-31 are drawn to a kit comprising a substrate and a TAstV-2 antigen that may be expressed from recombinant cells or present in a lysate, positive and negative controls and a labeled secondary antibody.

See the teachings of Schultz-Cherry et al. above. Although Schultz-Cherry et al. do not mention providing the conventional immunoassay formats discussed in columns 10-11 as kits, the physical components and ingredients used to complete the methods of detecting TAstV-2 antibodies render the instant kits prima facie obvious.

Claim 32 states that the kit further comprises "instructions". Copyright law controls printed content of a detailed protocol, and the printed content is not patentable. The claimed printed matter is not functionally related to any substrate and does not distinguish the invention from the prior art in terms of patentability. *In re Gulack*, 703 F.2d 1381, 217 USPQ 401 (Fed. Cir. 1983).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz-Cherry et al. as applied to claims 1-20 and 22-32 above, and further in view of Kim et al. (WO 92/20803).

Claim 21 states that the TAstV-2 antibodies detected are IgG and IgM.

Schultz-Cherry et al. do not discuss the type of antibody specific for TAstV-2. However, it is known in the art that IgM and IgG antibodies represent the presence of acute and chronic infections, respectively, in astrovirus infections, see lines 31-34 on page 23 of Kim et al. One of ordinary skill in the art at the time the invention was made would have been motivated to analyze a specific Ig antibody in a sample to characterize the infection. One of ordinary skill would have had a reasonable expectation of success for detecting IgM- or IgG-specific TAstV-2 antibodies in the immunoassays of Schultz-Cherry et al. because these antibodies are routinely used to detect astrovirus infection in immunoassays, see the previous citations of Kim et al.

Claims 1-8, 10-20 and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monroe et al. (US 5,625,049) and Koci et al. (Journal of Virology. 2000; 74 (13): 6173-6177).

See the summary of the claims above.

Monroe et al. teach a method of detecting the presence of human astrovirus serotype 2 antibodies (HAst-2) by providing a fluid sample from a suspected host animal, contacting the sample with an immobilized HAst-2 capsid antigen and detecting whether the sample comprises antibodies specific for the antigen. The fluid sample is derived from blood, serum, urine, feces, saliva or gastric juice and sample antibodies are detected by conventional immunoassays with secondary antibodies labeled with a reporter substrate. See column 8, line 42 to column 10, line 43. Monroe et al. does not teach or suggest detecting TAstV-2.

However, Koci et al. characterize TAstV-2 (admitted in the instant disclosure on page 2, lines 13-14). Koci et al. teach isolating and characterizing the virus genome from homogenized thymus and intestines of infected turkeys, see the entire reference.

One of ordinary skill in the art at the time the invention was made would have been motivated to detect the presence of TAstV-2, characterized by Koci et al., in the immunoassay of Monroe et al. to identify infected turkeys. One of ordinary skill in the art would have had a further motivation to detect the presence of TAstV-2 using the immunoassays of Monroe et al. for efficiency and ease. One of ordinary skill in the art would have had a reasonable expectation of detecting the presence of TAstV-2 of Koci et al. in the immunoassay of Monroe et al. because Monroe et al. teach detecting the presence of astrovirus using the capsid protein and Koci et al. teach the corresponding capsid protein of TAstV-2, see Figure 2 for example.

Although Monroe et al. do not mention providing the conventional immunoassay formats as kits, the physical components and ingredients used to complete the methods of detecting TAstV-2 antibodies render the instant kits prima facie obvious.

Claim 32 states that the kit further comprises "instructions". Copyright law controls printed content of a detailed protocol, and the printed content is not patentable. The claimed printed matter is not functionally related to any substrate and does not distinguish the invention from the prior art in terms of patentability. *In re Gulack*, 703 F.2d 1381, 217 USPQ 401 (Fed. Cir. 1983).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Monroe et al. and Koci et al. as applied to claims 1-8, 10-20 and 22-32 above, and further in view of Mueller-Lantzsch et al. (US 5,858,723).

Claim 9 states that the antigen is present in recombinant insect cells. Mueller-Lantzsch et al. teach that baculovirus is a conventional system used to expresses large quantities of heterologous protein with the necessary processing, see column 9, lines 48-54. Therefore, this system would have been a prima facie obvious alternative for expressing the capsid protein of TAstV-2 in lieu of the conventional mammalian cell lines listed by Monroe et al. in column 7.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Monroe et al. and Koci et al. as applied to claims 1-8, 10-20 and 22-32 above, and further in view of Kim et al. *supra*.

Claim 21 states that the TAstV-2 antibodies detected are IgG and IgM.

Neither Monroe et al. nor Koci et al. discuss the type of antibody specific for TAstV-2. However, it is known in the art that IgM and IgG antibodies represent the presence of acute and chronic infections, respectively, in astrovirus infections, see lines 31-34 on page 23 of Kim et al. One of ordinary skill in the art at the time the invention was made would have been motivated to analyze a specific Ig antibody in a sample to characterize the infection. One of ordinary skill would have had a reasonable expectation of success for detecting IgM- or IgG-specific TAstV-2 antibodies in the immunoassays of Monroe et al. and Koci et al.. because these antibodies are routinely used to detect astrovirus infection in immunoassays, see the previous citations of Kim et al.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Primary Examiner
Art Unit 1648